

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION**

IN RE K-V PHARMACEUTICAL) No. 4:11CV01816 AGF
COMPANY SECURITIES LITIGATION)

MEMORANDUM AND ORDER

This consolidated securities fraud class action is before the Court on Plaintiffs’ motion for reconsideration of the scope of the leave to amend their complaint, granted in the Court’s Memorandum and Order dated March 27, 2014. For the reasons set forth below, the motion shall be denied, and final judgment shall be entered in favor of Defendants.

BACKGROUND

Defendants are K-V Pharmaceutical Company and three of its officers (collectively, “K-V”). The putative class of Plaintiffs consists of all purchasers of publically traded securities of K-V between February 14 and April 4, 2011. This litigation is based on allegedly materially false and misleading statements and omissions made by K-V, during the class period, regarding K-V’s distribution and sale of the prescription medicine Makena.

As more fully explained in the Court’s March 27, 2014 Memorandum and Order, the gravamen of Plaintiff’s claims is that K-V knew or should have known that if it charged \$1,500 per dose for Makena as planned, the FDA would not enforce K-V’s exclusive marketing rights under the Orphan Drug Act (“ODA”), making it impossible for Makena, and in turn K-V, to be commercially successful. According to Plaintiffs, this knowledge rendered both K-V’s statements during a February 14, 2011 investor conference call, as well as its failure to mention during the call the likelihood of the FDA’s nonenforcement, materially false or misleading in violation of Section 10(b) of the Securities Exchange Act of 1934, as amended by the Private

Securities Litigation Reform Act (“PSLRA”), and Rule 10b-5 promulgated thereunder. One of these statements was that K-V would implement a financial assistance program for patients who could not afford Makena at the \$1,500 per dose price.

The allegation regarding K-V’s knowledge was based in large part on alleged warnings by three confidential witnesses (“CWs”) that if K-V charged \$1,500 per dose of Makena, the FDA would not enforce K-V’s exclusive rights. Indeed, K-V did charge the \$1,500 and the FDA did not enforce K-V’s exclusive rights, leading to the sharp decline in the value of Plaintiffs’ investments in K-V.

The Court concluded that the bulk of K-V’s challenged statements were protected by the safe harbor provision of the “PSLRA” because they were forward-looking and accompanied by meaningful cautionary language. Further, with regard to the omission of a statement that there was a risk of nonenforcement of Makena’s exclusivity due to the planned price for Makena, the Court concluded that the amended complaint failed sufficiently to plead scienter (a mental state embracing intent to deceive, manipulate, or defraud).

The Court concluded that Plaintiffs’ reliance on the CWs’ alleged statements to establish K-V’s scienter failed because the amended complaint did not allege sufficient facts from which the Court could conclude that the CWs knew or were in a position to know that the FDA would not, or very likely would not, enforce Makena’s exclusivity rights. The Court noted that such knowledge on the part of the CWs seemed “improbable in light of the FDA’s own statement that its decision was based on a ‘unique situation.’”

The Court rejected Plaintiffs' suggestion at oral argument that they could possibly further amend their amended complaint to state that the CWs had the requisite knowledge, as follows:

Plaintiffs have had ample opportunity to fully explore what the CWs knew and the basis for their supposed knowledge. By the time of oral argument, the case had been pending for over two years. The CWs are Plaintiffs' own witnesses to whom they had access at least since the filing of the amended complaint in July 2012. And given the questionable ability of Plaintiffs to establish K-V's required scienter based on the CWs, the Court does not believe that giving Plaintiffs leave at this point in the proceedings to amend their current complaint regarding this particular claim is warranted. This is especially true inasmuch as the Court finds K-V's statements with regard to FDA enforcement of exclusivity to be protected forward-looking statements.

(Doc. No. 116 at 24.)

The Court concluded that K-V's statement about the financial assistance program for patients who could not afford Makena at the planned price was not forward looking, but that the amended complaint was deficient with regard to the falsity of this statement. The Court afforded Plaintiffs leave to file a second amended complaint limited to how this statement was false. The Court granted K-V's motion to dismiss in all other regards.

K-V now asks the Court to reconsider the scope of its leave to amend, seeking the right to amend its allegations with respect to the CWs' knowledge that the FDA would not enforce Makena's exclusivity. The proposed new allegations include that one of the CWs informed K-V that even if the FDA sought to enforce exclusivity, its ability to do so was extremely limited due to its limited resources; that according to CWs that Plaintiffs have re-interviewed or new CWs, no comprehensive market research was conducted by K-V to support the pricing of Makena. Plaintiffs also assert that they are "prepared to provide greater background information

on all of the CWs in an amended pleading as well as several new CWs that will demonstrate the CWs had far greater experience and expertise in the area of pharmaceutical marketing, sales and pricing than did the members of K-V management who ignored their warnings” with regard to pricing Makena at \$1,500 per dose. (Doc. 119 at 3).

Plaintiffs state that they have no further allegations concerning the financial assistance program and do not intend to amend their allegations in that regard.

Defendants argue that the Court should apply the standard of Federal Rule of Civil Procedure 60(b) to K-V’s motion for reconsideration, and deny the motion pursuant to that standard.¹ They maintain that the motion should be denied even if the less-exacting standard of Rule 54(b)² applied because Plaintiffs’ proposed amendments do not present any new evidence that was not available earlier, and any amendment would be futile in light of the Court’s alternative holding that the statements now at issue were protected by the safe harbor, a conclusion Plaintiffs have not challenged. According to K-V, even under Rule 59(b), a motion

¹ Reconsideration under Rule 60(b) is appropriate only if the moving party can demonstrate one of the following:

- (1) mistake, inadvertence, surprise, or excusable neglect;
- (2) newly discovered evidence that, with reasonable diligence, could not have been discovered in time to move for a new trial under Rule 59(b);
- (3) fraud (whether previously called intrinsic or extrinsic), misrepresentation, or misconduct by an opposing party;
- (4) the judgment is void;
- (5) the judgment has been satisfied, released or discharged; it is based on an earlier judgment that has been reversed or vacated; or applying it prospectively is no longer equitable; or
- (6) any other reason that justifies relief.

² This rule allows a district court to revise a decision that adjudicates, but does not enter final judgment on, any but not all claims in an action with multiple claims.

for reconsideration should only be granted to correct manifest errors of law or fact or to present newly discovered evidence.

Plaintiffs reply that Rule 54(b) applies here, and that reconsideration under that rule is not limited to manifest error or the presentation of previously unavailable evidence. In their reply, Plaintiffs also question the Court's conclusions with respect to whether K-V's statements at issue were forward-looking.

DISCUSSION

The Court agrees with Plaintiffs that Rule 54(b) applies to Plaintiffs' motion for reconsideration as the Court did not yet direct entry of judgment as to any of Plaintiffs' claims. The standard for reconsideration under Rule 54(b) is not entirely clear. Some courts have expressed the lenient standard urged by Plaintiffs. *See, e.g., United States v. Renda*, 709 F.3d 472, 479 (5th Cir. 2013) ("Rule 54(b) authorizes a district court to reconsider and reverse its prior rulings on any interlocutory order for any reason it deems sufficient."). But in this Circuit and District the standard is stricter, such that a Rule 54(b) motion for reconsideration "may not serve as a vehicle to identify facts or raise legal arguments which could have been, but were not, raised or adduced during the pendency of the motion of which reconsideration was sought." *See Evans v. Contract Callers, Inc.*, No. 4:10CV02358 FRB, 2012 WL 234653, at *2 (E.D. Mo. Jan. 25, 2012) (citation omitted); *see also Chism v. W.R. Grace & Co.*, 158 F.3d 988, 992 n.4 (8th Cir. 1998); *Evans v. Contract Callers, Inc.*, No. 4:10CV2358 FRB, 2012 WL 234653, at *2 (E.D. Mo. Jan. 25, 2012) ("Although the Court has the power [under Rule 54(b)] to

revisit prior decisions of its own . . . [it] should be loathe to do so in the absence of extraordinary circumstances such as where the initial decision was clearly erroneous and would work a manifest injustice.”).

Here, under either standard for a Rule 54(b) motion, Plaintiffs’ motion fails. The Court gave careful consideration to the legal arguments Plaintiffs presented earlier in opposition to K-V’s motion to dismiss, and again now for reconsideration. None of Plaintiffs’ arguments for reconsideration are deemed sufficient by the Court. And though the Court granted Plaintiffs leave to amend with respect to the financial assistance program, they say they do not intend to amend in this regard. Thus, it appears that it is time for the Eighth Circuit Court of Appeals to consider the Court’s rulings, should Plaintiffs choose to file an appeal.

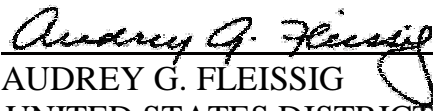
CONCLUSION

Accordingly,

IT IS HEREBY ORDERED that Plaintiffs’ motion for reconsideration is **DENIED**.
(Doc. No. 118.)

IT IS FURTHER ORDERED that Defendants’ motion to dismiss the complaint for failure to state a claim is **GRANTED**.

A separate Judgment shall accompany this Memorandum and Order.



AUDREY G. FLEISSIG
UNITED STATES DISTRICT JUDGE

Dated this 6th day of June, 2014.